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10/004,873	12/07/2001	Masashi Hakamata	Q67595	7375

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/004,873

**Applicant(s)**

HAKAMATA, MASASHI

**Examiner**

BJ Forman

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I, Claims 1-12 in papers filed 19 May 2003 is acknowledged.

Claims 13-20 are withdrawn from consideration.

Claims 1-12 are discussed below.

***Specification***

2. The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 1-12 are indefinite in Claim 1 because the claim is drawn to a method of image analysis. However, the claims do not recite method steps of image analysis. Furthermore, while the method steps detect spots, produce a template and effect analysis of the template, the claims are not limited to an “image” and do not recite steps of image analysis. As such, the claims are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: image analysis.

b. Claims 1-12 are each indefinite for the recitation “spot-like dropping” because it is unclear how “like” modifies the spot. It is suggested that the claims be amended to clarify.

c. Claims 1-12 are indefinite each for the recitation “effecting quantitative analysis” because it is unclear whether the recitation is a method step of quantitative analysis or merely “effecting” for analysis at some future point in time. It is suggested that the claims be amended to clarify.

d. Claims 2-12 are each indefinite because they are each drawn to the method of Claim 1 and recited method steps including the method steps of Claim 1. Therefore, it is unclear whether the methods of Claims 2-12 further comprise the recited method steps thereby repeating the method steps of Claim 1. As such, it is unclear what method steps are actually being claimed in each of the methods of Claim 2-12. For example, Claim 3 is drawn to the method of Claim 2 which is drawn to the method of Claim 1. Each of Claims 1-3 recite the first method step of “spot-like dropping”. However, it is unclear whether the method of Claim 3 is intended to contain 3 steps of “spot-like dropping” prior to hybridization. It is suggested that Claims 2-12 be amended to clarify.

e. Claims 6-8 are each indefinite for the recitation “the fluorescent dye for producing template data is contained in a polymer and which comprises the steps of causing the polymer to contain the specific binding substance”. However, it is unclear how the step of “a

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polymer... comprises causing the polymer..." modifies the dye. It is suggested that Claims 6-8 be modified to clarify.

f. Claims 11 and 12 are each indefinite for the recitation "the substance derived from a living organism and labeled with a fluorescent dye" because the recitation lacks proper antecedent basis in Claims 1 and 10. It is suggested that Claims 11 and 12 be amended to provide proper antecedent basis.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2 and 10 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Garner (U.S. Patent No. 6,160,681, issued 12 December 2000).

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As discussed above, the claims are indefinite because it is unclear whether an image is analyzed and because it is unclear whether the methods of Claims 2-12 repeat the method of Claim 1 in addition to the reiterated steps. For purposes of examination Claims 1-12 are interpreted as comprising the method steps recited in each claim.

As written the claims are interpreted as being drawn to a method comprising the steps of dropping a dye with a specific binding substance, irradiating the dye, photodetecting the dye, producing template data, producing a template and quantitative analysis. Some claims are further drawn to hybridizing a labeled target to the specific binding substance and irradiating and photodetecting the labeled target. It is noted that the claims do not require that the recited method steps are performed sequentially i.e. in the order they are recited.

Regarding Claim 1, Garner discloses a method comprising the steps of dropping spots (Column 8, lines 53-67) of a specific binding substance onto a substrate to form a plurality of spots (e.g. fluorescently labeled cDNAs, Column 9, lines 33-36), producing a template defining regions of interest (i.e. master grid or dot array, Column 11, lines 1-12) and quantitatively analyzing template (Column 10, lines 16-44).

Regarding Claim 2, Garner discloses the method comprising the steps of dropping spots (Column 8, lines 53-67) of a fluorescent dye together with a specific binding substance onto a substrate to form a plurality of spots (e.g. fluorescently labeled cDNAs, Column 9, lines 33-36), irradiating the spots with a wavelength to simulate the dye, photoelectrically detecting fluorescence emission (Column 8, lines 14-42) producing a template defining regions of interest (i.e. master grid or dot array, Column 11, lines 1-12) and quantitatively analyzing template (Column 10, lines 16-44).

Regarding Claim 10, Garner discloses the method comprising the steps of dropping spots (Column 8, lines 53-67) of a specific binding substance onto a substrate to form a plurality of spots (e.g. fluorescently labeled cDNAs, Column 9, lines 33-36), irradiating the spots with a light, photoelectrically detecting light from the spots (Column 8, lines 14-42)

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producing a template defining regions of interest (i.e. master grid or dot array, Column 11, lines 1-12).

7. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Feazel et al (U.S. Patent No. 6,100,030 issued 8 August 2000).

Regarding Claim 1-12, Feazel et al disclose a method of image analysis (Fig. 12) comprising the steps of dropping a dye with a specific binding substance, irradiating the dye, photodetecting the dye, producing template data, producing a template and quantitative analysis and further hybridizing a labeled target to the specific binding substance and irradiating and photodetecting the labeled target (Examples, Column 37, line 46-Column 39, line 25). Feazel et al specifically teach that both the specific binding substance (probe) and target are labeled (Column 23, lines 38-54) wherein the labels include Cy5 and Cy3 (Column 42-59) wherein the hybridization between the probe and target are on a second (i.e. subsequent) substrate (Column 4, lines 31-46) and wherein the irradiation, photodetection and template production is performed serially (Column 4, lines 42-46).

It is noted that the claims do not require that the recited method steps are performed sequentially i.e. in the order they are recited. It is further noted that the claims are drawn to a method "comprising" whereby additional method steps are encompassed. Because the claims are broadly drawn to encompass method steps performed in any order and because the claims are broadly drawn to a method utilizing the open language "comprising", the method steps of Feazel et al including any additional method step are encompassed by the broadly claimed methods.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 3-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garner (U.S. Patent No. 6,160,681, issued 12 December 2000) in view of Feazel et al (U.S. Patent No. 6,100,030 issued 8 August 2000).

Regarding Claims 3-9 and 11-12, Garner discloses various combination so the method comprising the steps of dropping spots (Column 8, lines 53-67) of a specific binding substance onto a substrate to form a plurality of spots (e.g. cDNAs, Column 9, lines 33-36), hybridizing a substance derived from an organism with the binding substance, irradiating the spots with a wavelength to simulate the dye, photoelectrically detecting light from the spots (Column 8, lines 14-42) producing a template defining regions of interest (i.e. master grid or dot array, Column 11, lines 1-12) irradiating the spots with a stimulating ray, photoelectrically detecting emission, defining regions to be quantified (i.e. subsequent array) and quantitatively analyzing template (Column 10, lines 16-44 and Column 11, lines 1-12). Furthermore, they teach the labels are comprised of any of the numerous fluorochromes and dyes well known labels e.g. energy transfer which clearly suggests that both the specific binding substance and target are labeled



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(Column 7, line 42-Column 8, line 3). But Garner does not specifically teach that the specific binding substance and the target are both labeled fluorescent dye.

However, Feazel et al teach a similar method wherein both the specific binding substance and the target are labeled with a fluorescent dye. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe and target labeling of Feazel et al to the target quantification of Garner. The motivation to do so comes first from Garner who suggest that both are labeled (Column 7, lines 42-46) and second from Feazel et al wherein they teach that labeling both target and probe provides for rapid and specific detection (Column 23, lines 38-53).

Garner teaches that the label comprises any one of numerous fluorescent dyes known in the art e.g. Cy3,Cy5, Fluor X (Column 7, line 42-Column 8, line 3). The specification repeatedly teaches the fluorescent dyes comprise Cy3,Cy5, Fluor X (e.g. pages 68-69) but the specification does not teach or define other dyes which are fluorescent dyes contained in a polymer comprising the steps of causing the polymer to contain the specific binding substance. While limitations from the specification are not read into the claims, Claims 6-8 are interpreted in light of the specification wherein the dyes are selected from Cy3,Cy5, Fluor X. As such, Garner teaches the dye as claimed (Column 7, line 42-Column 8, line 3).

#### **Prior Art**

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Bao et al (U.S. Patent No. 6,251,601) teach a method of image analysis comprising template production (Column 3).

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Shams (U.S. Patent No. 6,349,144) teach a method of image analysis and template production (Fig. 12).

### **Conclusion**

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1634  
July 18, 2003